



COMPLIANCE NEWS



This proposed rule will supplement existing FDA regulations, NFPA codes and JCAHO requirements . . .

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Proposed Regulations for Medical Gas Mix-ups and Contamination

by Dean Samet, CHSP - DSamet@ssr-inc.com

THE U.S. FOOD AND DRUG ADMINISTRATION ISSUED AN APRIL 10, 2006 proposed rule designed to make the contents of medical gas containers and cylinders more readily identifiable to help prevent deaths and injuries from “inadvertent use of incorrect medical gas or from use of contaminated medical gas.”

This proposed rule will supplement existing FDA regulations, NFPA codes and Joint Commission requirements or recommendations for the safe use of medical gases, such as oxygen, nitrous oxide and nitrogen.

While this FDA proposal would apply directly to medical gas manufacturers and distributors, it is meant to ensure that healthcare facilities and patients receive correct, appropriate high quality and safe medical gases.

FDA proposed regulation requirements for portable med gas containers:

- 1) Have gas use outlet connections (used to connect these containers to gas supply systems) that cannot be readily removed;
- 2) Be identified by labels that wrap all the way around the tops of these containers;
- 3) Have high-pressure medical gas cylinders painted according to an FDA-designated standard color-coding system that corresponds to the gases stored in them; and,
- 4) Be dedicated to medical use and not converted from industrial use.

Again, the proposed rule, if finalized, will apply to medical gas manufacturers and distributors. However, the intent of the proposed rule is to make the medical gas supplies of hospitals and other healthcare facilities safer for patients by making the contents of medical gas containers and cylinders more readily identifiable and reducing the likelihood of med gas mix-ups and contamination of medical and industrial gases.

For the full proposal and more information go to the FDA web site at www.fda.gov/cder/dmpq/MedGas_QA_20060410.htm. **SSR**

Considering Construction's Impact on Fire Safety

by Leo Old, MS, CIH, PE, CHFM - LOld@ssr-inc.com

Renovations, additions and new construction activities can present additional fire and life safety risks within healthcare facilities. Risks may include increased fuel loads, altered egress routes, hot work activities, and compromised fire suppression, detection and alarm systems. Associated with every construction project, hospital engineers, facility managers, and/or safety officers should consider the following issues:

- Interim Life Safety Measures (ILSMs) – JCAHO standard EC.5.50 requires hospitals to “determine when and to what extent one or more of the (interim life safety) measures” are implemented for a given project. EC.5.50 does not require that all 11 of the ILSMs be implemented for a construction project. Rather, the hospital determines which are necessary for a given construction project.
- *NFPA 241, Standard for Safeguarding Construction, Alteration, and Demolition Operations* – Although NFPA 241 is not fully adopted by JCAHO and may not be fully adopted by your local authority having jurisdiction, it is referenced by *NFPA 101, Life Safety Code*. NFPA 101 requires the means of egress (i.e., horizontal and vertical travel elements) in an area undergoing construction, repair or improvements to comply with NFPA 241. Nevertheless, NFPA 241 may serve as a useful guidance document when establishing your own fire prevention policies for construction projects.
- Temporary Construction Barriers – NFPA 241 requires that renovation, construction or demolition work zones be separated from occupied areas with a wall having a one-hour fire resistance rating.



NFPA 241 permits non-rated walls to be used if sprinkler protection is provided.

- Fire Extinguishers – NFPA 101 requires portable fire extinguishers be provided in healthcare occupancies. NFPA 241 also requires fire extinguishers be placed within construction areas. Both NFPA 101 and NFPA 241 require installation and maintenance of fire extinguishers to comply with *NFPA 10, Standard for Portable Fire Extinguishers* (NFPA 10).

Consequently, fire extinguishers within construction

areas should be treated in the same manner as those in occupied areas. Construction-area fire extinguishers should be inspected monthly and receive annual maintenance, as specified in NFPA 10.

- Hot Work – Prior to any hot work (welding, cutting, brazing, soldering or similar activity), the hospital should issue a hot work permit to the contractor performing the work. *NFPA 51B, Standard for Fire Prevention during Welding, Cutting and Other Hot Work*, provides precautions to be executed during hot work. Such precautions may include relocating combustibles at least 35' away, using fire-retardant guards or shields, providing a fire extinguisher in the work area and implementing a fire watch.
- Flammable Liquids – Contractors may introduce flammable liquids into the healthcare construction environment. Flammable liquids should be stored within approved safety cans or other containers. *NFPA 30, Flammable and Combustible Liquids Code*, provides size limits and specifications for containers of flammable liquids.

Contractors may not be aware of these issues. Hospital engineers, facility managers and safety officers should communicate such concerns to contractors prior to start of construction. Effective communication of these fire safety concerns to contractors should contribute to a fire-safe healthcare environment during construction projects. **SSR**

JCAHO EC Advisory Bulletin: ECAB #03-2006 Alcohol-Based Hand Rubs (ABHR) Gel and Foam Dispensers

by Dean H. Samet, CHSP - DSamet@ssr-inc.com

In a March 2006 announcement, the Joint Commission on Accreditation of Healthcare Organizations officially recognized the April 2004 National Fire Protection Association's Tentative Interim Amendment (TIA) changes to the 2000 and 2003 NFPA 101 Life Safety Code® as well as the Centers for Medicare and Medicaid Services' Conditions of Participation, Section 482.41, March 2005 amendment of CMS Interim Final Rule regarding the use and installation of alcohol-based hand rub dispensers. (See May 2005 SSR *Compliance News* for NFPA and CMS list of criteria). Recently the International Code Council (ICC) in their 2006 International Fire Code (IFC) Section 3405.5 has also adopted and/or developed similar language.

The JCAHO has clarified its position on the installation of these dispensers. Per the NFPA, CMS and IFC, the ABHR dispensers should not be placed directly over or "adjacent" to an ignition source such as an electrical outlet, electrical switch or device, etc. Although the term "adjacent" is not defined by the NFPA, CMS or IFC, the JCAHO is now defining "adjacent" as a distance of at least six inches as measured from the center of the dispenser.

The Joint Commission also provided some guidance on the ABHR "foam" dispensers. Unlike the "gel" dispensers, the foam dispensers contain a propellant to dispense the foam. This product was not included in the original computer modeling performed on behalf of the American Society for Healthcare Engineering (ASHE) for the "alcohol-gel" dispensers. However, the Joint Commission is presently allowing the installation and use of the ABHR foam dispensers as long as the aforementioned NFPA and CMS criteria is complied with as well as the manufacturer's recommendations for these alcohol-based hand rub dispensers. **SSR**

JCAHO EC Advisory Bulletin: ECAB #04-2006 United States Pharmacopoeia- National Formulary (USP-NF) USP Tests and Assays Chapter 797, Pharmaceutical Compounding, Sterile Preparations

by Dean H. Samet, CHSP - DSamet@ssr-inc.com

The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) announced in their April 2006 edition of Joint Commission Perspectives, that they "will not survey for compliance with the details of USP 797." This is a departure from previously published material where accredited organizations were to have completed action plans per USP Ch.797 requirements by January 1, 2008. Now it is left up to the accredited organizations to determine how best to "comply with the requirements specified in USP 797, and what time frames for compliance are reasonable." (*Continued on page 4*)


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The Perspectives article stated that, "The Joint Commission requires, as part of [their] standard MM.8.10, that organizations evaluate literature for new technologies and successful practices relevant to improving their medication management system. The Joint Commission considers USP 797 a valuable set of guidelines—contemporary-based safe practices—that describe a best practice for establishing safe processes in compounding sterile medications. USP 797 guidelines, while more specific than Joint Commission standards about sterile medication preparation and infection control, can help organizations comply with applicable Joint Commission standards." It goes on to say that an

accredited organization can decide its compliance in this regard "with advice from experts and stakeholders, such as the organization's director of pharmacy, risk manager, facility manager, microbiologist, infection control staff, and legal counsel, taking into account state laws and regulations."

Note: Some states require compliance with USP 797. Check with your state's Board of Pharmacy for their specific requirements for the design, construction, operation, inspection and testing of pharmacy sterile compounding areas. 

Publications & Seminars

Seminars in 2006

May 13	American Industrial Hygiene Conference & Exposition, Chicago, IL, "Life Safety Engineering"
May 16	Veterans Administration VISN 10 Safety & Health Meeting, Columbus, OH, "JCAHO EC Update"
May 23	<i>Facility Care</i> Magazine Audio Conference, "Life Safety Code"
June 6	NFPA Town Hall Meeting, Orlando, FL, "JCAHO EC Update"
June 8	Georgia Society for Hospital Engineers, St. Simon's Island, GA, "Overcoming Infection Control Challenges During Healthcare Construction"
June 15	Triad Engineering Conference, Plano, TX, "Life Safety Code"
June 16	Texas Association of Healthcare Facilities Management, Austin, TX, "NFPA 99"
July 11-12	ASHE Annual Meeting, Boston, MA, "A-Z of BMP" and "Misinterpreted Aspects of the Life Safety Code"
August 10	West Virginia Society for Healthcare Engineering, Snowshoe, WV, "Rx for Emergency Power Reliability"
September 7-8	Georgia Society for Healthcare Engineers, McRae, GA, "Advanced Management of Emergency Power Testing" and "Risk Assessments in EC Management Plans"
October 18-20	Decision Health 2006 EC Summit, Orlando, FL, "Unannounced Surveys: Ready or Not" and "Infection Control's Impact on the Environment of Care"
October 24-26	Healthcare Design Symposium, Chicago, IL, "Post Occupancy Evaluations for Healthcare Facilities"
November 2-3	Midwest Healthcare Engineering Conference, Indianapolis, IN, "Unannounced Surveys and New EC Targets" and "Facility Electrical Maintenance"



Compliance News

A Newsletter Dedicated to Accreditation, Regulatory Compliance and Facility Management Issues for Healthcare Executives and Facility Managers

For more information
please contact

DEAN SAMET, CHSP
800-545-6732
DSamet@ssr-inc.com
www.ssr-inc.com